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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,913	07/12/2002	Sylvia Collicc-Jouault	33339/244859	7074

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EXAMINER

MAIER, LEIGH C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/069,913	COLLIEC-JOUAULT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 January 2004.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_ .

5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1-12 have been amended and are under examination. As discussed in the previous Office action, the claims have been amended to recite a method distinct from the one that had been examined in the first action on the merits (FAOM). Applicant rightly notes that the notice of non-responsiveness was written in the form of a US practice restriction, whereas the present application is a Section 371 application, requiring a finding of lack of unity to restrict. As cited in the FAOM, the product used in both methods is known in the art (See NARDELLA), thus negating unity of invention. However, in the interest of compact prosecution, the new method has been examined, and an action on the merits is set forth below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are recited in such a way where the intention appears to be further limiting the method, but what is recited is how the medicine is intended to be used, thus

rendering the claims vague and indefinite. Applicant might consider “method of claim 1 wherein venous thrombosis is treated or prevented” etc.

***Claim Rejections - 35 USC § 102***

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by MILLET et al (Thromb. Haem., 1999).

MILLET teaches the subcutaneous administration of a LMW (8 kDa) sulfated fucan obtained by acid hydrolysis to a subject. The step of the method is disclosed, thereby anticipating the present method. See abstract and page 391, section with sub-head “Antithrombotic Effects.”

The fucan is not produced by radical polymerization, but has the required MW and is used for the same purpose as Applicant. Therefore, this product appears to meet the limitation of the claim. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over NARDELLA et al (WO 97/08206) in view of COLLIEC et al (US 5,321,133) and MILLET et al (Thromb. Haem., 1999).

The invention is drawn to the treatment or prevention of vascular thrombosis by administration of a sulfated polysaccharide obtained by radical depolymerization of a fucan having a MW of not more than 10,000 g/mol. Dependents recite dosages and methods of administration.

NARDELLA discloses highly fractionated sulfated polysaccharides obtained by radical depolymerization. This product has anticoagulant properties. See abstract; pp 3-4; and Tables I-V. The reference does not specifically teach the use of the anticoagulant polysaccharide product to treat or prevent vascular thrombosis.

COLLIEC teaches that sulfated fucans having molecular weight of about 5 kDa to about 40 kDa, with a preferred range of less than 20 kDa, have utility as anticoagulants and antithrombotics and teaches their use in the prevention of venous thrombosis. The

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polysaccharide is administered by a variety of methods, including subcutaneously. See especially col 5-6. Especially recommended is the use of fractionated products that allow for a concentrated solution. See col 6, lines 38-40. The reference does not exemplify the use of a polysaccharide having a MW of less than 10 kDa.

MILLET teaches as set forth above. This reference confirms that depolymerized fucan retain antithrombotic activity and have potentially weaker hemorrhagic effect. See abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer the fucan disclosed by NARDELLA to treat/prevent venous thrombosis. COLLIEC had suggested the use of a LMW (less than 20 kDa) fucan for the treatment of venous thrombosis, and MILLET had confirmed that LMW fucans indeed retain the therapeutic activity necessary for said treatment. The product disclosed by NARDELLA is highly fractionated as suggested by COLLIEC and disclosed as being an anticoagulant. In view of the art of record, one of ordinary skill would reasonably expect success in using this product for the present method.

With regard to the recited dosages, both COLLIEC and NARDELLA discuss the comparison of the fucan products with known heparin products in *in vitro* methods for the determination of appropriate dosages. It would be within the scope of the artisan to do likewise in order to optimize the effective dosage with routine experimentation.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over NARDELLA et al (WO 97/08206) in view of COLLIEC et al (US 5,321,133) and MILLET et al (Thromb. Haem., 1999) and further in view of RACCHINI et al (US 5,458,568).

NARDELLA, COLLIEC, and MILLET teach as set forth above. The references do not teach the prevention of arterial thrombosis.

RACCHINI teaches the use a balloon to administer antithrombotics, such as heparin, by diffusion in combination with angioplasty. See col 5, beginning line 49, continuing through col 6, line 47.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer the fucan disclosed by NARDELLA as described by RACCHINI for the purpose of preventing arterial thrombosis with a reasonable expectation of success. As discussed above, MILLET had taught that LMW fucans retain antithrombotic activity. Therefore, one of ordinary skill would reasonably expect success in using this product as described by RACCHINI.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

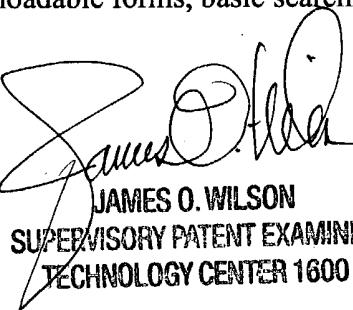
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

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Patent Examiner  
April 2, 2004